



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

AF

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,357	09/10/2001	Janet A. Warrington	3355.1	9510
22886	7590	11/28/2005	EXAMINER	
AFFYMETRIX, INC ATTN: CHIEF IP COUNSEL, LEGAL DEPT. 3380 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051				ZEMAN, MARY K
		ART UNIT		PAPER NUMBER
				1631

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/955,357	WARRINGTON, JANET A.
	Examiner	Art Unit
	Mary K. Zeman	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 September 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-12,36-38 and 46-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 10-12, 34-36 and 46-48 are pending in this application.

The indicated allowability of claims 10-12, 34-36, 46-48 is withdrawn in view of the newly discovered reference(s) to WARRINGTON et al (2000). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 34-36 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over WARRINGTON et al (2000) in view of CHEE (US 6,368,799).

The claims are amended to recite methods of correlating gene expression with genotype. Two populations of individuals are genotyped at SNP positions, and their gene expression profiles obtained. Measures of normalized expression are obtained, and used to identify genes segregating with the genotype.

WARRINGTON, J.A. et al. (*Physiol Genomics* 2: 143-147; 4/27/00) compares expression profiles for two separate groups of individuals, and identifies genes linked to each population. WARRINGTON compares adult human individual samples with fetal human individual samples. Normalized measures of gene expression are obtained for each gene in each population. The algorithms used by WARRINGTON appear to be the same for determining measures of normalized change between gene expression levels. WARRINGTON provides programmed computers and computer program products which perform the calculations. WARRINGTON does not genotype each population at SNP positions *prior* to comparing the expression profiles.

CHEE (US 6,368,799; already of record) discloses methods of correlating expression levels of gene profiles with genotypes, and haplotypes. At columns 8-9, Chee discloses how

polymorphisms (Single nucleotide polymorphisms, or SNPs) are identified in populations or differing individuals, then the gene expression profiles are correlated with those genotypes. Gene expression levels, SNP genotypes and other data are subjected to normalization and association methods. Clustering analysis can also be performed on the data. "The genotype of an individual with respect to one or more polymorphisms within the gene is then correlated with the expression level of gene transcript in the same individual." Column 9. These appear to be the same methods as claimed by specific algorithm in claims 11-12, 35-36 and 47-48. While CHEE does not spell out any mathematical formulae, the underlying principles appear to be the same. Up to 100,000 differing probes can be assessed (col 10). Chee discloses that these correlations can be performed by programmed computers, or systems. These systems comprise computer readable media, and software for carrying out the methods.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have genotyped the individual populations of WARRINGTON by the methods of CHEE, and then analyzed the gene expression profiles. One of skill in the art would have been motivated to have performed the simple genotyping step, as it would allow linkages to be made between individual genetic information with gene expression which may be correlated with disease. One of skill in the art of gene expression profiling would have had a reasonable expectation of success at producing the claimed invention, as the SNP genotyping uses the same types of GENECHIP technology used by both WARRINGTON and CHEE.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Art Unit: 1631

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

MKZ
MARY K. ZEMAN
PRIMARY EXAMINER

Av (63)
11/15/05